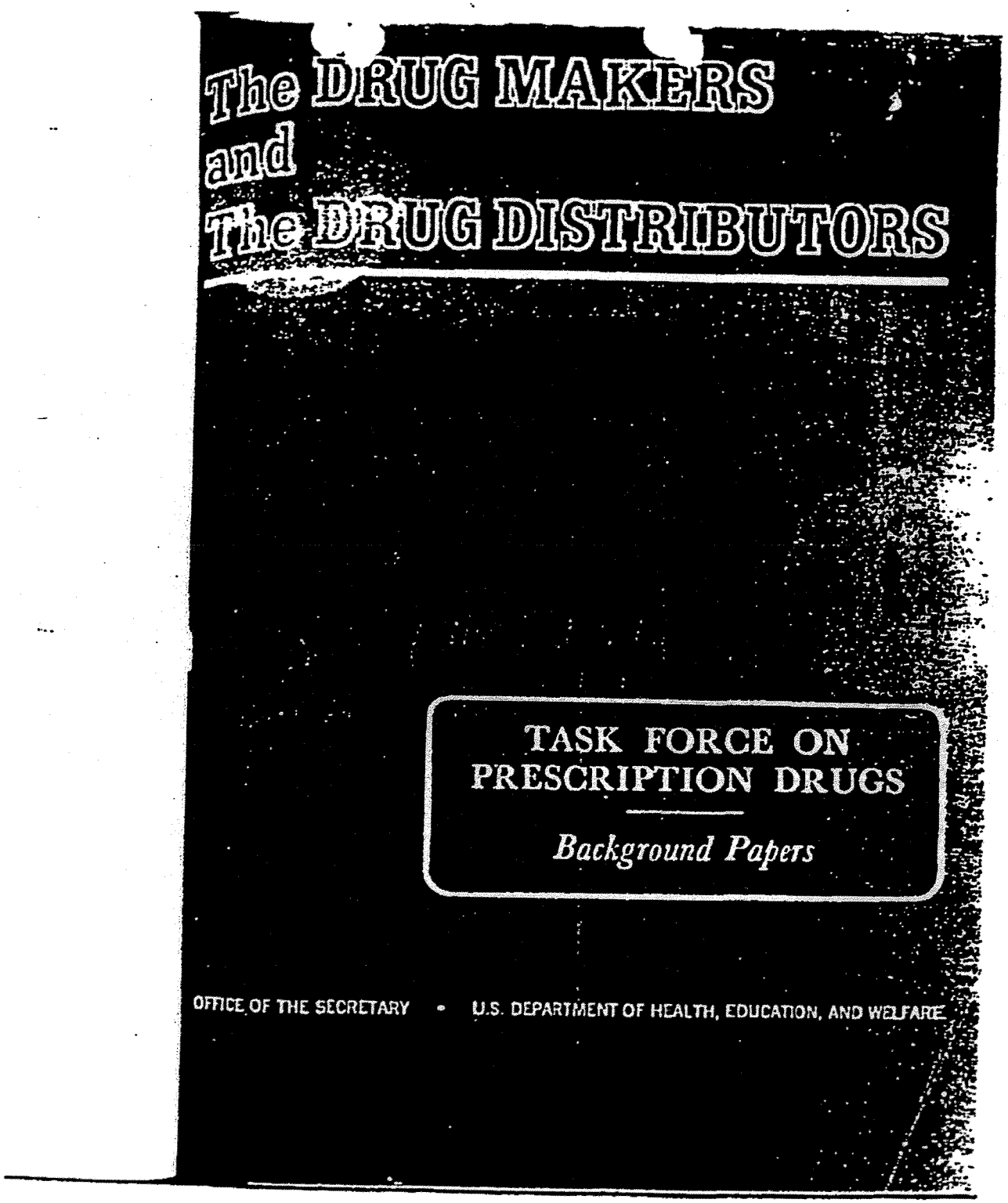
EXHIBIT 9


The DRUG MAKERS
and
The DRUG DISTRIBUTORS
TASK FORCE ON
PRESCRIPTION DRUGS
Background Papers
OFFICE OF THE SECRETARY • U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

TASK FORCE ON PRESCRIPTION DRUGS

Background Papers

The DRUG MAKERS and The DRUG DISTRIBUTORS

December 1968

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TASK FORCE ON PRESCRIPTION DRUGS

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INTRODUCTION

IN MAY OF 1967, acting upon a directive from the President, John W. Gardner—then Secretary of Health, Education, and Welfare—established the Task Force on Prescription Drugs. The charge to the Task Force appeared to be simple—

Undertake a comprehensive study of the problems of including the cost of prescription drugs under Medicare.

Few assignments, however, have been more complex. Essential for the Task Force study was objective information on the health needs and resources of the elderly; the present patterns of drug use; the nature of drug research, production, and distribution; current drug insurance programs in the United States and abroad; reimbursement methods and administrative approaches; legal and fiscal aspects; and the pharmacological and clinical aspects, including the intricate problem of chemical and clinical equivalency of generic products.

In some instances, the necessary data were readily available. In others, they were not—and the Task Force found it necessary to undertake its own special research projects.

The information derived from these studies serves as the basis for the findings and recommendations which are being published separately by the Task Force. In addition, however, this basic material appears to have great value for the Congress, many State and Federal governmental agencies, the medical and pharmacy communities, the drug industry, health insurance organizations, health educators, and consumer groups. Accordingly, the Task Force is publishing the detailed results of its studies in a series of background papers.

This volume, combining studies on the manufacture and the distribution of prescription drugs, is one such publication. It was prepared by the Task Force staff in cooperation with many consultants, both governmental and nongovernmental, whose invaluable assistance is gratefully acknowledged. Special appreciation goes to the many representatives of the pharmaceutical industry, the pharmacy profession, and the medical and scientific communities who kindly made available much unpublished material to the Task Force and provided their valuable advice, guidance, and proposals to the Task Force staff.

It is evident that the present high quality of health care enjoyed by most Americans—though by no means by all of them—is a testimonial in considerable part to the many accomplishments of the American drug industry and the American pharmacist. But it is also clear that the level of health care in this country is not yet high enough to justify any complacency or slackening of our efforts. Serious problems still exist in the development and marketing of drugs, and realistic steps must be taken—with imagination, understanding, courage, and boldness—if our goals are to be achieved. The nature of some of these problems and the steps that can be taken are indicated in this volume.

Philip R. Lee

PHILIP R. LEE, M.D.

CHAPTER 7

INDUSTRY PRICES

In the mass of debate, controversy, and Congressional hearings of the past decade dealing with the drug industry, perhaps the most heated issue has concerned the attempt to determine whether drug prices are or are not "too high." Consequently, the manner in which prices are determined, the behavior of prices over time, and the price discounts to various purchasers all bear on any understanding of that controversy and on any evaluation of the various points of view heard within it.

Drug Distribution. Prescription drug companies typically promote brand-name drugs of all types to the Nation's practicing physicians, dentists and, to a lesser degree, wholesalers and retail pharmacists.

Today, there are perhaps 191,000 medical doctors and doctors of osteopathy in private practice, 110,000 dentists, and 120,000 active pharmacists. In addition, approximately 45,000 physicians are in training and 55,000 are in government service or are engaged in professional work other than private practice. (*88*)

The industry's commercial marketing of prescription drugs, however, is accomplished not through practitioners but largely through wholesalers who sell to independent and chain store pharmacies, or through direct sale to such pharmacies.

In 1966, 47.5 percent of domestic sales was to wholesalers, down nearly one percent from 1965. Direct sales to retail outlets of all types accounted for 29.6 percent, slightly lower than in 1965.

Direct sales to hospitals (private, State, and local government) and the medical profession accounted for 17.2 percent of domestic output, while the Federal government, including hospitals and other government installations, purchased 4.8 percent. Miscellaneous purchasers acquired the remaining less than one percent (*56*) (see Figure 8).

The Discounting System

Manufacturers' prices of prescription and over-the-counter drugs are found principally in *Drug Topics Red Book* and the *American Druggist Blue Book*, both standard price directories published annually. Normally, the *Red Book* and *Blue Book* listings quote the maximum price to the retailer, whether he buys from a wholesaler or directly from the manufacturer. However, *Red Book* and *Blue Book* do not reflect the actual manufacturers' prices to wholesalers and retailers, which are determined by the amounts of various kinds of discounts. Nor do these publications always reflect the prices in the most recent editions of each company's product catalog.

The price discounting system starts with the company's catalog prices. Wholesalers and retailers, hospitals, and government agencies often pay markedly different prices for the same drug and dosage form, as described later. Some prices quoted in the *Red Book* and *Blue Book* appear generally to be unchanged over long periods, though both the wholesaler and the community pharmacist are not being charged the list prices.

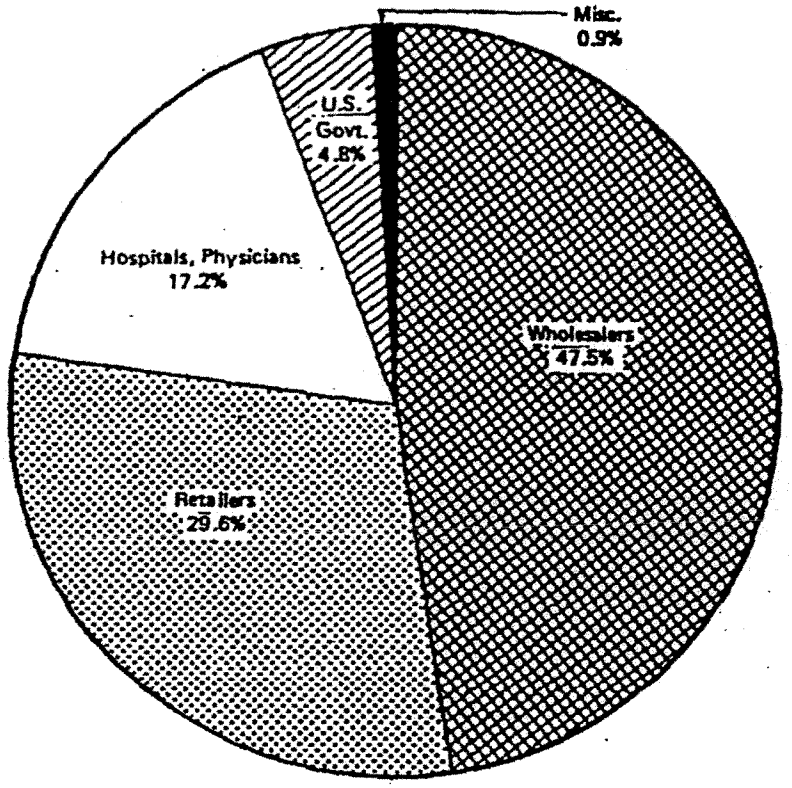
For example, about 200 drug products accounted for 67 percent of all prescriptions filled in 1966. The *Red Book* prices for one or more dosage forms of at least one-quarter of these drugs had not changed from the 1959 to the 1968 editions. (*63*, p. 71) Slightly more than one-half of the drugs with unchanging prices were brand-name products—most presumably protected by patents—made by the largest manufacturers.

The prices of most drugs on the list of 200 have fluctuated to some extent during the last decade but the disparity in manufacturers' listed prices and what their customers really pay makes reasonable comparisons extremely difficult. In this respect, various indices used by business economists and the government to measure changes in prescription drug prices are vulnerable to misinterpretation.

A number of factors may cause the disparity between some of the published drug prices and the amounts actually entered on the customer's invoice.

First, the introduction of a new dosage form can mean a price change for a drug whose other existing forms remain unchanged in price. The overall price of the product does not necessarily remain static because the price of several older dosage forms holds steady.

Figure 8.—Domestic Distribu. . of Human Dosage Form Prescription ugs by Percent of Manufacturers' Sales, 1966



SOURCE: PHARMACEUTICAL MANUFACTURERS ASSOCIATION, 1968. MANUFACTURERS' SALES OF ETHICAL PHARMACEUTICALS. ANNUAL SURVEY OF PMA MEMBERS, AUGUST 1967.

Second, the catalog price is not necessarily what the company recovers overall per unit, even if it sells directly to retailers. Volume discounts, bonus goods, and other trade incentives all operate to decrease receipts per unit.

A drug company official has said:

"Every manufacturer selling direct has his own selling plan. These plans have little uniformity or consistency but in general offer extra discounts from the net trade price. These discounts might be based on yearly volume, volume over quota or size of individual order. So far this discount structure is fairly simple. These percentage figures appear in the various catalogues." (44)

Discount deals can become complicated, h pointed out:

"We run into such items as the free goo deal. Free goods of one with eleven or two wit ten are common and effective promotional a lowances. However, some manufacturers ha lost sight of the promotional purpose of fr goods deals and are using this method to unde sell competition in some trade classes witho the across-the-board reduction. Use of physicia samples for this purpose is also common."

And he added:

"To further complicate the picture, we ha wholesalers passing on most of their disco

to the retailer, and retailers spl...ng their handling allowance with the hospital, all in good free competitive form in the best tradition of Robinson-Patman. A rather good description of the pharmaceutical marketplace was given by a leading professor in business administration recently when he referred to it as 'an oriental bazaar.'"

Another reason for a relative lack of apparent catalog price movement is that for products available from more than one source, the catalog price constitutes an "umbrella" beneath which the company can maneuver against competing products. The higher the umbrella, within limits, the more elbow room there is for maneuvering. (*63*, p. 71)

Pricing Factors

Generally speaking, the information considered by a drug manufacturer in pricing a new product includes direct manufacturing costs, overhead, clinical factors, marketing and distribution costs, and profit potential.

The cost of goods sold normally is less than half the selling price of a new prescription drug. Research, marketing, administration, and other overhead items must be allocated over a range of products in the manufacturer's line.

Clinical factors are based on the nature of the condition the drug is designed to treat. How many people suffer from the condition? How effective is the drug in treating it? How much of the drug should the patient take and how often? What dosage forms will be needed? What does the patient pay for existing drugs for treating the same condition? Again, some of the answers must be estimates. (*63*, p. 72)

Another factor is whether the drug is used for acute or chronic conditions in the young or the aged. Those who take drugs for prolonged periods (perhaps for life), it is contended, should be offered medication at the lowest possible cost so that it does not become too heavy a burden. In the view of some observers in the drug industry, patients suffering from chronic conditions deserve special consideration. Similarly, manufacturers have been advised to support efforts to make prescription drugs available at lower cost to the indigent, to those not gainfully employed, and especially to the aged. (*15*, pp. 58 *et seq.*)

Actually, the industry's response antedates this suggestion. For example, drugs designed to treat uncommon illnesses—where the market is limited—are often sold at or below manufacturer's cost and in some cases may be supplied without charge.

Profit potential and the cost of promoting a new drug to physicians and others are intimately related. One reason is that therapeutic value does not guarantee wide sales, at least initially. Word of therapeutic efficacy demonstrated by such products as sulfa-drugs, penicillin salts, and corticosteroids spread quickly, but these were atypical. Much more common are the chemical workhorses that provide more modest therapeutic gains—often variations of existing drug products—and they need marketing help.

A drug ideally should be priced so that it can absorb not only the costs of marketing required to realize its full profit potential, which requires another estimate, but also a large share of its research and development costs. Its price must also reflect a share of the costs of unsuccessful research.

When a drug company takes the trouble to apply for a trademark, it is usually for a drug product with high profit potential. Price and profit on trademarked drugs—along with marketing costs on them—tend to be high. Conversely, price and profit on drugs sold without a trademark tend to be low. Since established generic-name products generally are well known to the physician, they are not promoted extensively. Accordingly, the manufacturer of such products can normally offer them at low prices.

The latitude allowed a drug company in charging what the market will bear is apparently determined by the uniqueness of its product. A major breakthrough into an entirely new therapeutic field obviously will find no competitors waiting to offer a reasonable substitute. Thus, the innovator can dominate the market in that new therapeutic group, and charge what he considers appropriate until a competitor develops a more attractive product.

For products that are not unique—and this applies to the majority of innovations coming from the pharmaceutical industry—the situation is different. If comparable substitutes in their therapeutic group already exist, a firm can hope to achieve only a limited share of the market, regardless of price, unless it undertakes a heavy promotion campaign.

Introductory Price. When a new product is first introduced, a drug company tends to price it rela-

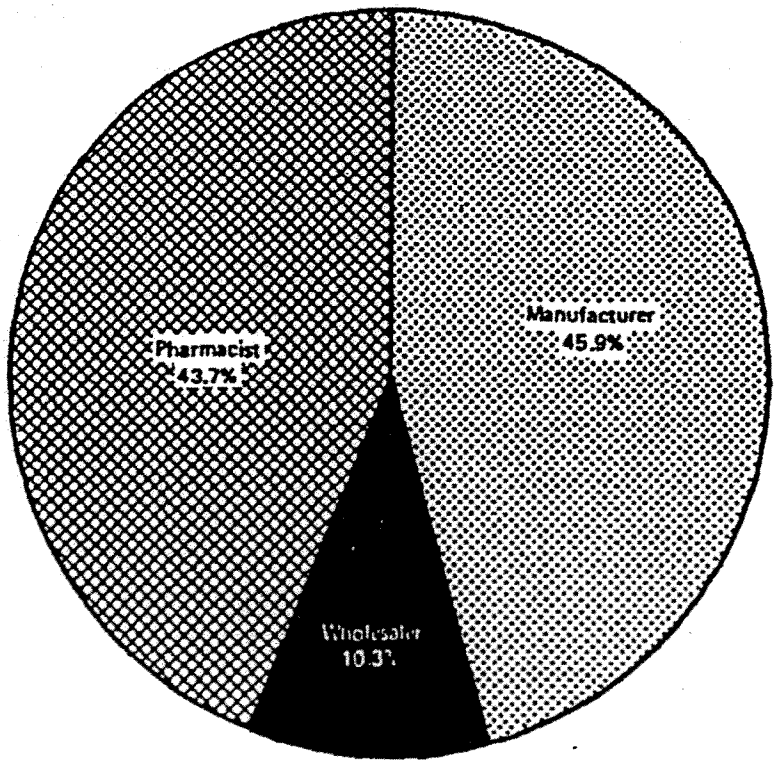
tively high. It might be priced to produce a specified annual income, with anticipated price reductions, inflationary increments and competitive developments figured in, over the length of the patent life, and perhaps beyond. A relatively high initial price is encouraged by the fact that price competition at the manufacturer's price probably will account for less than half the price to the patient. (*63*, p. 73)

Figure 9 shows how an "average" prescription cost is divided among manufacturer, wholesaler, and retailer; Figure 10 indicates how the manufacturer's share of the cost is divided.

Price Increases. Although the average prescription price of an original prescription (as distinct from a refill) was $3.56 in 1966, according to the National Prescription Audit (R. A. Gosselin & Co.), the average retail price of an original prescription for a newly introduced product was $4.88, rising from $3.95 in 1962. One reason for the increase, industry sources say, is that the average price level of today's highly potent and complex drugs is higher than the average for older, less potent drugs. It has been suggested that some of the gradual rise may be due to an increase in units or tablets per prescription. This may apply to some products but not to those drugs which require constant supervision of the patient, with the writing of prescriptions at relatively frequent intervals. (*15*, p. 58) With some of the newer, more powerful drugs, the overall cost of treatment may actually be less than it was with older medications because fewer doses are required and the course of the disease is halted earlier.

The originator of a new drug usually sets the selling price on the basis of considerations already described. This price seems to become a guide for all succeeding drugs with similar therapeutic action and dosage forms. A British writer has suggested that "the pricing policy of the leader

Figure 9.—Components of Prescription Cost of $3.20 Among Manufacturer, Wholesaler, and Pharmacist, 1965 (See also Figure 11, page 55)



SOURCE: DRUG TOPICS, APRIL 4, 1966.

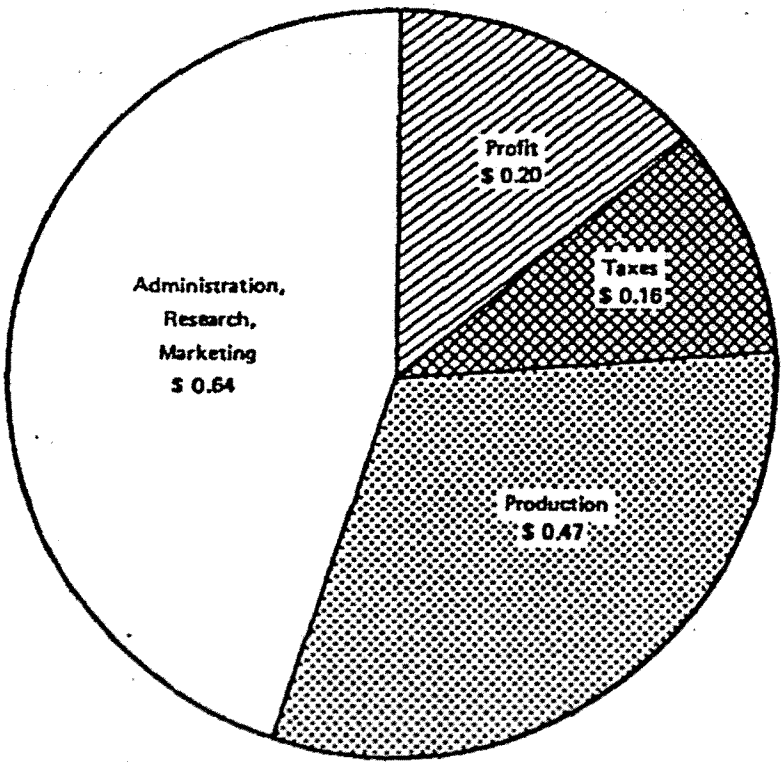
is bound to have a dominant effect on the policy of rivals." (*30*)

In general, it appears, new items appearing on the market are priced higher than the items they displace—perhaps because the new items are more potent, more sophisticated, need less frequent use, or possess some other characteristic that justifies the price differential. But it may be that the higher price is really just that—a rise in price, if not in the actual price tag, at least in what the consumer must pay for his drugs, now that he is buying the new item rather than the old.

Price Decreases. When they occur, price declines may be of different sorts and the result of different circumstances. Some of these price changes are of only academic importance to the consumer. For example, some early breakthrough drugs, such as the first antibiotics and steroid hormones, were priced originally at very high levels, reflecting their high development costs and the primitive production processes employed. As improvements in manufacturing methods occurred, prices fell—and often fell drastically. Reductions of this sort obviously are highly significant from the consumer's point of view.

Reductions of another sort are more common but may or may not be meaningful. These involve products that have been on the market longer than their actual or expected commercial life. For some of them, the price cuts may reflect the producer's recognition of their past contribution to

Figure 10.—Components of Manufacturer's Share of Prescription Drug Costs of $1.47, as Received From Wholesaler



SOURCE: HOW PATIENTS' PAYMENTS FOR DOCTORS' PRESCRIPTIONS ARE DIVIDED BETWEEN DRUG STORES, WHOLESALERS AND PHARMACEUTICAL MANUFACTURERS. ADAPTED FROM LILLY DIGEST, NATIONAL WHOLESALE DRUGGISTS' ASSN. OPERATING SURVEY AND DRUG TRADE NEWS FINANCIAL SURVEY OF DRUG TRADE SUPPLIERS, DRUG TOPICS, APRIL 4, 1966.

profits and he may thus be induced to lower these profit margins. To consumers, such reductions may be very meaningful. For others, though, the price cuts may be competitive moves—and usually futile ones—to offset the introduction of new items which threaten to displace them in the market, and thus are of less significance to patients who receive prescriptions calling for the new items.

An example of this type of price cutting was reported recently in the drug trade press, as follows:

> "Lilly, whose basic product patent on V-Cillin and V-Cillin K expires July 31, licenses both Abbott and Wyeth. Lilly sells the bulk pharmaceuticals to Wyeth, and Abbott manufactures its own bulk materials. Thus, Lilly's steady price reductions (*10 to 22.5 percent, effective June 3: Ed.*) can be regarded partly as an effort to discourage new competition from entering the market when the patent expires." (*18*)

Price Indices

The Bureau of Labor Statistics publishes an annual Consumer Price Index for nine categories of drugs encompassing 14 specially selected products. This BLS index has suggested a decline in prescription drug costs since 1957–59. But, as discussed elsewhere, a different measure is provided by three major surveys of average prescription prices of all drugs, which uniformly demonstrate a gradual rise in average prescription prices at the retail level. (*82*)

The Wholesale Price Index, also published by BLS, has shown a decline in manufacturers' prices from a level of 100 in 1961 to 90.4 in January 1968. This decrease reflects the prices of about 50 selected drugs which have been examined periodically, and which have generally remained steady or decreased in price, or in a relatively few instances have increased. But the wholesale index does not reflect the impact of the introduction of new and more expensive single or combination products or new dosage forms, which tend to raise average prescription prices. (*82*)

Substitution Effect

In any discussion of prescription drug price indices and "average prescription prices," the industry notes that cognizance must be given to the trend for newer and more effective drugs which may limit or substitute for hospitalization and, in many cases, for the time and expense of physicians and other health care personnel. Within the hospital, this substitution effect occurs not only with new products—which may shorten the duration of the patient's stay—but also through new dosage forms or methods of applicaton which economize on other costs, e.g., reducing the number of medication errors, cutting down on nursing time and otherwise increasing hospital efficiency. Despite the higher costs of some of the new substitute drugs, the drug industry maintains that the share of the total health care dollar spent for prescription drugs has declined from 11.7 cents in 1957 to 9.1 cents in 1966—a fact which the industry says profoundly affects the task of projecting future health care expenditures both in the public and private sectors.